

## Message Text

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ORIGIN HEW-06

INFO OCT-01 EA-09 ISO-00 OES-05 ARA-10 EB-07 /038 R

DRAFTED BY: DHEW/FDA:JRWEINROTH, M.D.

APPROVED BY: OES/APT/BMP:WJWALSH III

DHEW/OIH:MACODDING

EA/ROC:CWFREEMAN INFO

ARA/CAR:DASTRASSER INFO

EA/PRCM:OVARMSTRONG INFO

----- 098187

P 022248Z MAR 76

FM SECSTATE WASHDC

TO AMEMBASSY PORT AU PRINCE PRIORITY

AMEMBASSY MANILA PRIORITY

AMEMBASSY TAIPEI PRIORITY

AMCONSUL HONG KONG PRIORITY PRIORITY

UNCLAS STATE 050911

E.O. 11652: N/A

TAGS: OGEN, ETRD, TBIO, HA, HK, RP, TW

SUBJECT: FDA ADVISORY - FAULTY MANUFACTURING PRACTICES  
AND POSSIBLE PRODUCT NON-STERILITY (RECALL NO. D-217-  
218/6)

1. FDA ADVISES THAT:

PRODUCT INVOLVED:

BETASYNPLEX NIPHANOID WITH B12 SYNTHETIC CRYSTALLINE  
VITAMIN B COMPLEX FACTORS NIPHANOID (CYANOCOBALAMIN  
VITAMIN B12) 5 MCG, THIAMINE HCL 30 MGS., RIBOFLAVIN  
10 MGS., NIACINAMIDE 100 MGS., CALCIUM PANTOTHENETE  
5 MGS., PYRIDOXINE HCL 5 MGS., INJECTABLE: WINTHROP  
PRODUCTS, INC., NEW YORK, NY 10016. 50 AMPULES/BOX;  
OR IN A COMBINATION PACK WITH AN AMPULE OF VITAMIN C  
(ASCORBIC ACID INJECTION 500 MGS.) 25 COMBINATION PACKS/  
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BOX. (RECALL D-217-6)

THE BETASYNPLEX IS ALSO SHIPPED IN A COMBINATION PACKAGE:  
"CONTAINS 1 AMPULE (5 ML.) OF STERILE BETASYNPLEX  
NIPHANOID AND 1 AMPULE (5 ML.) ASCORBIC ACID INJECTION XXX  
500 MG. ASCORBIC ACID WITH 250 MG. SODIUM BICARBONATE XXX  
WINTHROP XXX". (RECALL D-218-6)

THE OUTER CARTON OF 25 COMBINATION PACKS IS SIMILARLY  
LABELED.

THE ASCORBIC ACID IS NOT BEING RECALLED EXCEPT  
COINCIDENTALLY IN THE COMBINATION PACK.

LOT NUMBERS:

PRODUCT: BETASYNPLEX NIPHANOID, CONTROL NO.'S:  
113KK, 450KK, 229KL, 230KL, 620KL, 441KN, 466LA, 069LC,  
375LC, 445LC, 500LD, 387LE, 089LF, 439LF, 540LF, 532LN,  
133LO, 210ND

DISTRIBUTION: FROM 1/1/74 UNTIL 10/1/75

MANUFACTURER:

STERLING DRUG, INC.  
33 RIVERSIDE AVE.  
RENSSELAER, NY 12144

RECALLING FIRM:

WINTHROP PRODUCTS  
90 PARK AVENUE  
NEW YORK, NY 10016

REASON FOR ADVISORY (RECALL):

THROUGH VARIOUS INSPECTION REPORTS AND AT CONFERENCES  
HELD WITH THE CORPORATION'S RESPONSIBLE OFFICIALS, FDA  
ALLEGED THAT THE PRODUCTS WERE NOT AND HAD NOT BEEN  
MANUFACTURED IN CONFORMANCE WITH CURRENT GOOD MANU-  
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FACTURING PRACTICE REGULATIONS AND THAT THERE WAS A  
QUESTION OF PRODUCT STERILITY. AFTER SEVERAL MORE  
MEETINGS AND IN-DEPTH REVIEWS OF BATCH RECORDS OF  
"STERILE" DRUG PRODUCTS, THE FIRM INSTITUTED A RECALL OF  
THE INJECTABLE PRODUCTS INVOLVED.

2. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES  
TO DETERMINE IF THEY HAVE BEEN INFORMED OF THE DETAILS

OF THE RECALL AND IF THEY HAVE RECEIVED THE RCA GLOBAL CABLES SENT BY THE FIRM TO ALL FOREIGN DISTRIBUTORS ON AN INDIVIDUAL BASIS CONCERNING THIS RECALL. POSTS MAY ALSO WISH TO CONTACT HOST COUNTRY DRUG CONTROL AUTHORITIES INFORMING THEM OF THE RECALL SO THAT THEY MAY TAKE SUCH ACTIONS AS THEY DEEM APPROPRIATE.

3. FOREIGN CONSIGNEES AS FOLLOWS:

1. STERLING PRODUCTS INTERNATIONAL, INC., WINTHROP LABS., INC. TAIPEI, TAIWAN, CHINA

2. STERLING PRODUCTS INTERNATIONAL, INC., MACOTTI, RIZAL, REP. OF PHILIPPINES

3. STERLING DRUG, INTERNATIONAL, INC., HONG KONG

4. MR. JEHN CRAAN, PORT-AU-PRINCE, HAITI. INGERSOLL

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## Message Attributes

**Automatic Decaptioning:** X  
**Capture Date:** 01 JAN 1994  
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**Current Classification:** UNCLASSIFIED  
**Concepts:** MANUFACTURES, VITAMINS, RECALLS, FOOD & DRUG REGULATIONS  
**Control Number:** n/a  
**Copy:** SINGLE  
**Draft Date:** 02 MAR 1976  
**Decaption Date:** 01 JAN 1960  
**Decaption Note:**  
**Disposition Action:** n/a  
**Disposition Approved on Date:**  
**Disposition Authority:** n/a  
**Disposition Case Number:** n/a  
**Disposition Comment:**  
**Disposition Date:** 01 JAN 1960  
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**Disposition History:** n/a  
**Disposition Reason:**  
**Disposition Remarks:**  
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**Document Unique ID:** 00  
**Drafter:** DHEW/FDA:JRWEINROTH, M.D.  
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**Errors:** N/A  
**Film Number:** D760080-0923  
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**Handling Restrictions:** n/a  
**Image Path:**  
**ISecure:** 1  
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**Previous Handling Restrictions:** n/a  
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**Review Date:** 04 JUN 2004  
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**Secure:** OPEN  
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**TAGS:** OGEN, ETRD, TBIO, HA, HK, RP, TW  
**To:** PORT AU PRINCE  
MULTIPLE  
**Type:** TE  
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